

4326. Misbranding of sulfathiazole tablets and sulfadiazine tablets. U. S. v. Standard Drug Co. and Ottice H. Blankenship. Pleas of guilty. Fine of \$200 against company and \$150 against individual. (F. D. C. No. 34829. Sample Nos. 46553-L to 46555-L, incl.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against the Standard Drug Co., a partnership, Sheffield, Ala., and Ottice H. Blankenship, a partner in the partnership.

NATURE OF CHARGE: On or about July 30 and August 12 and 15, 1952, while a number of *sulfathiazole tablets* and *sulfadiazine tablets* were being held for sale at the Standard Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 2, 1954. The defendants having entered pleas of guilty, the court fined the partnership \$200 and the individual \$150.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4327. Misbranding of Tryptacin tablets. U. S. v. 38 Dozen Bottles * * *. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 33948. Sample No. 19876-L.)

LIBEL FILED: October 20, 1952, District of Minnesota.

ALLEGED SHIPMENT: On or about October 8, 1952, by Rhodes Pharmacal Co., Inc., from Cleveland, Ohio.

PRODUCT: 38 dozen bottles of *Tryptacin tablets* at St. Paul, Minn.

RESULTS OF INVESTIGATION: An advertisement in a Minneapolis Sunday newspaper for September 28, 1952, announced the availability of "New Tryptacin An Achievement of Science" at various drug stores in the area. The advertisement consisted of a full page ad reading, in part, as follows: "We have proved it! In actual clinical X-ray tests patients showed almost complete healing in 4 weeks * * * New Tryptacin relieves Acid Pain of Diagnosed Stomach Ulcers, Acid Indigestion, Gas, After-Eating Distress * * * X-Rays revealed that a number of ulcer patients tested showed almost complete healing in 4 weeks."

LABEL, IN PART: (Bottle) "Tryptacin Rhodes For the Temporary Relief of Excess Gastric Acidity 100 Tablets Sole Distributors Rhodes Pharmacal Co., Inc., Cleveland, Ohio * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that its label failed to state the conditions or diseases for which the article was intended to be taken, and its label failed also to bear adequate directions for use in the treatment of such conditions and diseases.

DISPOSITION: Rhodes Pharmacal Co., Inc., appeared as claimant and filed an answer on October 30, 1952, denying that the product was misbranded. Thereafter, the Government filed a motion for summary judgment on the grounds that since the newspaper advertisement on its face recommended and sug-

gested the product for the treatment of stomach ulcers and since the labeling did not specify stomach ulcers as one of the conditions or diseases for which the product was offered, there was no fact in dispute and the product was therefore misbranded. The court denied this motion when the claimant submitted affidavits tending to raise a question of fact as to the meaning of the advertisement. Thereafter, a set of written interrogatories and a set of requests for admissions were served upon the claimant. The claimant filed answers to the requests for admissions and to certain of the interrogatories, accompanied by objections to the remainder of the interrogatories.

On May 25, 1953, the court sustained some of the objections and overruled the others. Answers to the interrogatories on which objections had been overruled were filed subsequently, and on June 17, 1953, the case came on for trial before the court without a jury. At the conclusion of the trial, the matter was taken under advisement by the court; and, on September 4, 1953, the court handed down the following opinion:

BELL, District Judge: "This is a seizure action brought under Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 334 (a). It was begun by the filing of a libel of information charging that the seized article was a drug which had been shipped in interstate commerce by the Rhodes Pharmacal Company of Cleveland, Ohio, and that the article was misbranded while in interstate commerce under 21 U. S. C. 352 [502] (f) (1) by reason of the failure of its labeling to bear adequate directions for use. The charges arise out of the following facts.

"A full page advertisement for 'Tryptacin' appeared in the St. Paul Pioneer Press at approximately the same time that the drug was offered for sale in that city. The advertisement makes prominent reference to stomach ulcers as well as other conditions, while the label on the bottle of 'Tryptacin' bears no reference whatever to stomach ulcers. Libelant alleges that the advertisement recommends and suggests the drug for treatment of stomach ulcers and that the failure of the labeling of the drug to state that it is to be used in treating 'stomach ulcers,' causes the directions for use in the labeling to be inadequate and the product to be misbranded under 21 U. S. C. 352 [502] (f) (1). Libelant further charges that the directions for use which appear on the labeling do not, regardless of whether the words 'stomach ulcers' appear in the labeling, constitute adequate directions for use in the treatment of that disease. Claimant's position is that the advertisement represents only that 'Tryptacin' is intended for use as an antacid and that the directions for use on the label are adequate for that usage. There is no issue as to the composition of 'Tryptacin' or its effect on the human body.

"The first question raised deals with the meaning to be given to the language of the advertisement. It is clear to me that the full page advertisement offers 'Tryptacin' to the public as something more than an antacid or a palliative for acid pain. In the upper left hand corner of the advertisement there are described clinical tests in which ulcer patients 'Showed Almost Complete Healing' after treatment with 'Tryptacin.' This language, in my opinion, can have been put into the advertisement for no other purpose than to cause the sufferer from stomach ulcers to believe that the drug would give more than relief from pain of stomach ulcers, and that it will, in fact, provide a cure. Nor does the language of the advertisement dealing with the power of 'Tryptacin' to neutralize stomach acidity overcome the impression conveyed by the portion of the advertisement referred to above.

"The contention of claimant that the drug is sold only to give symptomatic relief from acid pain requires the portion of the advertisement relating to the 'healing' of stomach ulcers to be disregarded and that the Court ignore the obvious import of the advertisement as a whole. This would manifestly place an unreasonable interpretation on the advertisement. 'The ultimate impression upon the mind of the reader arises from the sum total of not only what is said but also of all that is reasonably implied.' *Aronberg v. Federal Trade Commission*, 132 F. 2d 165, 167 (C. A. 7). I can see no reason for placing any language at all dealing with the healing of stomach ulcers

in the advertisement if 'Tryptacin' is offered only as a palliative for the relief of acid pain. See: *Bradley v. United States*, 264 Fed. 79 (C. A. 5); *United States v. 46 Cartons * * * 'Fairfax Cigarettes,'* (D. N. J., 1953). Unreported, but summarized in 21 LW 2606, June 16, 1953. If it is to be used as a simple antacid, the full page ad is entirely out of place. Certainly the reader of the advertisement would not gather from it the idea that 'Tryptacin' is for temporary palliative relief alone, whether he is one of 'the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze,' *United States v. 62 Packages * * * 'Marmola Prescription Tablets,'* 48 F. Supp. 878, 887 (W. D. Wis.); or 'the ordinary person who is neither savant nor dolt, who lacks special competency with reference to the matter at hand but has and exercises a normal measure of the layman's common sense and judgment,' *United States v. 88 Cases * * * 'Bireley's Beverage,'* 187 F. 2d 967, 971 (C. A. 3).

"In addition to reading and examining the advertisement, I base my finding as to the impression conveyed by the advertisement upon the evidence presented on that point. Libelant's witnesses, Dr. James N. Mosel and Dr. Howard P. Longstaff, experts in the field of advertising and marketing psychology, presented exhaustive analyses of the content of the advertisement and the effect which it was intended to have upon the prospective purchaser of the drug. Such testimony is admissible to determine the meaning of an advertisement. *Federal Trade Commission v. National Health Aids, Inc.,* 108 F. Supp. 340 (D. Md.).

"Moreover, Dr. Mosel introduced evidence relative to two hundred individuals whom he surveyed concerning the impression which they received from the 'Tryptacin' advertisement. A substantial portion of those interviewed indicated that they received the impression from the advertisement that 'Tryptacin' would 'stop,' 'cure' or otherwise bring about some permanent relief of ulcers. The forms filled out by the individuals questioned, interview cards, and tabulations made by Dr. Mosel of the answers received, were placed in evidence by Libelant.

"Other evidence of libelant which I considered in reaching my opinion as to the meaning of the advertisement included testimony of two persons who purchased 'Tryptacin' in the belief that the advertisement offered a cure for stomach ulcers, and the testimony of libelant's witness, Dr. Moses Barron, a specialist in internal medicine, who has treated many cases of stomach ulcers. Dr. Barron testified that in his opinion the ulcer patient would receive from the 'Tryptacin' advertisement the impression that the drug was offered as a cure for stomach ulcers. An expert medical witness is qualified to express such an opinion. *Charles of the Ritz Distributors Corporation v. Federal Trade Commission,* 143 F. 2d 676 (C. A. 2).

"Claimant's evidence on the import of the language of the advertisement consisted of the testimony of two representatives of a firm which handles 'Tryptacin' advertising and testimony of a number of physicians. The two advertising men testified (one on deposition) that in their opinion the advertisement offered 'Tryptacin' as a means of relieving acid pain and not of curing stomach ulcers. They also testified that they had showed the advertisement to a number of their associates in the advertising business, to newspaper censorship boards and to other persons, and inquired as to the impression which the advertisement conveyed. Both witnesses testified that not a single person questioned received the impression that the advertisement offered a cure for stomach ulcers. The doctors who testified for claimant stated that they had discussed the meaning of the advertisement with doctors, nurses, patients and other persons, and again that no person received from the advertisement the impression that the product would cure stomach ulcers. In no case did the witnesses offer any written evidence concerning such interviews, and it does not appear that such discussions were systematically conducted. The likelihood of error or prejudice developing in the course of such interviews would seem to be great, particularly since none of the witnesses of claimant, including both advertising men and doctors, were qualified by education or experience in the taking of formal public opinion surveys.

"The second question which I have found it necessary to answer is, having established that the advertisement offers a cure for stomach ulcers, are the directions for use adequate in the treatment of that disease. Libelant urges

that the labeling directions are not adequate simply by failure of the labeling to include a statement that the drug is to be used for 'stomach ulcers.'¹ That such a requirement is a requisite of adequate directions for use is borne out by the decisions. The principle was well stated in *United States v. Various Quantities* * * * '*Instant Alberty Food*,' 83 F. Supp. 882, 885 (D. C. D. C.) :

The words "adequate directions for use" necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment.

See also: *Alberty Food Products, a partnership, et al v. United States*, 194 F. 2d 463 (C. A. 9) ; *Colgrove v. United States* 176 F. 2d 614 (C. A. 9).

"Libelant also charges that the directions for use on the label of 'Tryptacin' are not adequate because, even if they were followed, a cure from stomach ulcers would not result. On this point, Libelant's witness, Dr. Barron, who possesses impressive qualifications, including the fact that he has diagnosed and treated numerous cases of stomach ulcers in the course of his practice, testified that the directions for use as they appear on the bottle label of 'Tryptacin' are not adequate. Dr. Barron gave as reasons for this statement the fact that every case of stomach ulcers must be treated as an individual problem; that other drugs as well as antacids are sometimes used in the treatment of stomach ulcers and that different antacids are used in different types of cases; that factors other than the administration of drugs are involved in the healing of an ulcer; that untreated or improperly treated stomach ulcers may become cancerous and unresponsive to surgery; and that stomach ulcers is a disease which should not be treated except under the supervision of a physician. Dr. Hugh A. McGuigan, who testified for claimant and who also possessed extensive qualifications in the fields of pharmacology and therapeutics, stated that in his opinion the directions for use on the label of 'Tryptacin' give to the user of the product sufficient directions to enable intelligent and safe self-treatment. Dr. McGuigan testified on cross-examination, however, that diet and rest, in addition to administration of an antacid, and other drugs, are sometimes factors in the treatment of stomach ulcers. In this last statement, Dr. McGuigan agreed in effect with Dr. Barron. It is apparent to me that the directions for use are not complete and consequently are inadequate.

"Findings of Fact, Conclusions of Law and an Order for Judgment will be entered accordingly."

In accordance with the above opinion, the court made its findings of fact and conclusions of law; and, on September 15, 1953, the court entered a decree of condemnation and destruction.

4328. Adulteration and misbranding of laxative quinine tablets. U. S. v. 75 Packages * * *. (F. D. C. No. 36214. Sample No. 56166-L.)

LIBEL FILED: December 29, 1953, Northern District of New York.

ALLEGED SHIPMENT: On or about September 2, 1952, from Worcester, Mass.

¹ The Secretary of Health, Education, and Welfare, acting under Section 701 (a) of the Act, 21 U. S. C. 371 (a), has promulgated the following interpretative regulations of Section 502 (f) (1) of the Act; 21 U. S. C. 352 (f) (1) :

21 C. F. R. 1,106 *Drugs and Devices: Directions for use.*—(a) *Adequate Directions for use.* "Adequate directions for use" means directions under which the layman can use a drug . . . safely and for the purpose for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug . . . is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug . . . is commonly used; . . .